WHAT IS MEDICAL NECESSITY: WHO PRACTICES MEDICINE?
FINDINGS AND RECOMMENDATIONS

I. INTRODUCTION

A. Organizations Are Practicing Medicine

Today, doctors and patients who agree on a course of necessary care may have that course altered by either delay or denial by an HMO or its utilization management designee. In theory, the opportunity to measure an impending medical decision against outcomes research, practice guidelines and relevant clinical algorithms, should ultimately work to patients' benefit. Some have argued that prior authorization/concurrent review is a key element separating managed care from traditional indemnity insurance. In addition to controlling costs, prior authorization/concurrent review can, in some cases, strengthen the quality of care by identifying procedures, tests or other treatments that may be unnecessary or contribute to errors. But the evidence of effectiveness is mixed.

The perception that treatment decisions are being reviewed by an appropriately credentialed physician, with adequate knowledge of the case at hand, is also mixed. In some cases, care may be compromised when a practitioner for adults is asked to render a pediatric opinion. Some have argued that certain children and adults with chronic disease would benefit from receiving their primary care from specialistsin the chronic disease. , While major stakeholders in the health care industry may disagree, the public perception is that the health plan reviewers are a heterogeneous group with mixed qualifications and that prior authorization/concurrent review sometimes focuses too heavily on cost and causes inappropriate delays or denials in care without due medical cause.

B. Cost Matters When Practicing Medicine

Purchasers, employers and consumers want slower growth in the cost of medical care and less costly health benefit arrangements. Yet, everyone expects maximal care when they become sick. Some consumers are not confident that they are receiving the highest quality of care when health plans and providers endeavor to practice cost-effective medicine by limiting selected services. , Legislators are trying to respond to constituents who have become mistrustful of the health care system.

C. Legislators Are Practicing Medicine

Unfortunately, while trying to solve these problems, the concern has been raised that legislators are practicing medicine without a license. Nationally and locally politicians are, implicitly if not explicitly, legislating medical practice body part by body part. The respected New England Journal of Medicine has declared that "medical imperialism is obsolete." The Task Force believes that the practice of medicine is a multi-disciplinary, multi-professional, team effort and physicians are no longer the sole arbiters of medicine. However, Congress and the California Legislature should not be medical practice team members. Politics should not determine medical practice. Appropriately credentialed professionals practicing scientific, evidence-based medicine should be the arbiters of cost-effective medical care. They should also be responsible for continuously improving the quality of medical care.

D. Variation in Practicing Medicine Clouds What is Medically Necessary

A basic premise is that doctors and other providers want to practice excellent, high quality medicine. Yet, research shows wide variations in both medical practice and resource use, without evidence of corresponding differences in either medical need or health outcomes. Significant practice pattern variation, however, raises important and complex questions. "Which rate of surgery or therapy is right?" "Are some patients being treated more conservatively with the same or better outcomes?" "Do certain rates of surgery or therapy reflect patient preferences and values more than others?" "What is the effect on a population's health?"

Variation also suggests that providers sometimes differ on what is medically necessary. In addition, some patients may want unnecessary services. The behavior of both physicians and patients is frequently driven by the inherent uncertainty in medical care. The need to reduce this uncertainty and consequent variation is compelling and challenging.

The practice of medicine depends on the interrelationship of diagnostic evaluations, clinical judgments, surgery, therapies and drugs, and the interaction and communication with patients. A review of a physician's pattern of medical decisions is very valuable when it can be done over a long enough period of time and with enough treatment and outcome data points to be able to statistically evaluate the physician's delivery of care. This evaluation should be done using state of the art information about clinical outcomes relative to the resources prescribed. This evaluation would provide a more scientific basis for establishing medically necessary, high quality care and accountability for medical practice.

E. Accountability in Practicing Medicine

The Medical Practice Act, a state law, assures that only qualified professionals make medical decisions. The Act defines the regulatory structure for licensure and allows for the Medical Board to discipline individuals if their practice endangers patients. Patients have redress for negligent actions by providers through the tort system.

Current law states that parties that participate directly in medical decisions that negligently affect clinical outcomes are responsible for liability. However, the Employee Retirement Income Security Act of 1974 (ERISA), a federal law, protects most health plans from this responsibility in the case of private sector employees and their families by allowing the plans to claim that utilization decisions are not medical decisions, rather, administration of an employee benefit. The courts have upheld this defense in general. In California, if courts have held otherwise, plaintiff awards have been subject to the Medical Injury Compensation Reform Act (MICRA), a state law, which imposes a $250,000 limit on the pain and suffering component of the damage award. Currently, ERISA plaintiffs are only eligible to recover money for the covered benefit and are not able to collect compensatory or punitive damages. ERISA limitations only permit plaintiffs to collect damages from an individual provider, not a medical group, IPA or health plan

Some courts in other states have held that a health plan and its medical director can be liable for denying coverage for certain procedures and can be disciplined by the state Board of Medical Examiners. Some people in California would like to impose the same standard.

Historically, the practice of medicine has relied upon regulation and civil liability controls to ensure the quality of care. Currently, HMOs are held accountable for their medical decision-making by the DOC for the approximately 40-50% of the market that is not covered under ERISA. While some HMOs delegate treatment and decision-making responsibilities to the medical groups, IPAs and other utilization management designees with whom they contract, the HMOs retain the responsibility for ensuring that their contractors comply with all of the provisions of the Knox-Keene Act. Currently there is no designated state regulatory authority that directly oversees the practice of medicine by medical groups/IPAs, as organizations.

ERISA laws do not apply to insured federal, state, municipal and self-employed individuals. As noted above, the preemption applies to the approximately 50-60% of the market, or those insured by the private sector in self-funded plans, that are covered under ERISA. It is this latter group that does not enjoy the same level of civil liability protection under the ERISA laws. More importantly, before any tort controls come into play, a patient must suffer an egregious and negligent event. All parties would benefit if the egregious and negligent event never happened in the first place.

II. FINDINGS AND RECOMMENDATIONS

A. Modify Prior Authorization/Concurrent Review

Decision quality should be improved by encouraging the use of practice guidelines, clinical pathways, careful selection and pre-credentialing of providers, retrospective utilization review and outcomes research in medical decision making. If a provider's referral patterns are appropriate and outcomes are good, the provider should be considered to have met a "gold standard" and the HMO should cease to require prior authorization/concurrent review for a finite period of time. Many alternatives to prior authorization/concurrent review are possible. There is room in the marketplace for a variety of innovative, incremental and expedited referral programs. , However, for innovations to occur, better data interchange is needed.

Many health plans delegate utilization review and management to their contracting medical groups/IPAs and other independent utilization management designees. Those health plans that delegate this responsibility, cannot monitor quality and compliance without encounter data. To be useful, encounter data should include diagnoses and procedures at the treatment level, information which medical groups have to date viewed as proprietary. Health plans should create incentives for medical groups and IPAs to provide such data. Ideally, the private sector will correct this data communication problem.

Purchasers should be encouraged to work with the scientific advisory arms of the health plans and medical groups to implement specific practice guidelines, clinical pathways and outcome studies for modifying the prior authorization process/concurrent review process. Patients with catastrophic diseases deserve special consideration. For example, in certain cancer cases treatment and therapy is time sensitive and delays or denials of care can have severe and unintended consequences. In many of these cases there are existing, accepted and respected clinical guidelines. (needs FN) Prior authorization/concurrent review should not be a barrier to care in these cases. In all situations, it is important to recognize that medical science and practice are constantly changing and a rigid codification of medical practice should be avoided.

Recommendation 1

a. The Task Force recommends to the major public and private purchasers that they incorporate provider pre-credentialing and the use of practice guidelines, clinical pathways, retrospective review (as opposed to prior authorization/concurrent review) and outcomes-based data into their contracts with health plans.
b. The Task Force recommends to the health plans, medical groups/IPA s and their designees , that they develop statistically valid data on patterns of care and patient outcomes. These data sets should then form the basis on which alternatives to prior authorization can be based.
c. The Task Force recommends to the health plans, and their designees that they develop and implement strategies that allow providers, demonstrating a "gold standard" range of practice, to practice medicine with automatic approval Health plans should develop appropriate and periodic review mechanisms to ensure that providers continue to demonstrate a "gold standard" range of practice.
d. The Task Force recommends to the health plans and their designees that they eliminate prior authorization/concurrent review for patients with catastrophic conditions (for example pediatric oncology patients) being treated by pre-credentialed providers.
e. The Task Force recommends to the legislature that: if by 2002 the private sector has not sufficiently modified the prior authorization/concurrent review process to recognize "gold standard" ranges of care or an equivalent modification, the lead HMO regulatory agency should make the necessary changes a requirement of health plan licensure.

B. Improve Formulary Effectiveness

Ideally, the appropriate practice of medicine effectively integrates clinical judgment, diagnostic evaluations, surgery, therapies and drugs to form and inform, clinical pathways, practice guidelines, and outcomes research. Pharmaceutical prescribing practices and costs are an important and much debated component of

this process. Pharmaceutical costs are rising rapidly; formularies are a necessary tool to manage them. To lower pharmaceutical costs and maintain affordable drug coverage, a case can be made that the individual physician's choice of drugs should be informed, guided and perhaps constrained by a committee of his or her peers. Flexibility should be built into this process to allow for individual physician and patient variation. It is not appropriate to apply strict population standards to individual patients when prescribing drugs. Some drugs work for some patients, but not for others. The involvement of practicing physicians in formulary development is key.

Provider groups in California have an average of 15 managed care contracts. This means that when prescribing a drug, a physician may have to consult several if not 15 drug formularies. Providers have to figure out which health plan covers their patient, then which drugs are in its formulary, and then spend time on the phone requesting exceptions. This is bound to raise administrative costs and complexity and reduce efficiency and effectiveness. The situation can be worse--indeed bordering on the impossible--for the doctor in individual practice who belongs to several IPAs, each of which contracts with 15 different managed care plans.

Recommendation 2:

a. Health plans should permit medical groups, or groups of groups, capable of assuming the management and financial risk for a drug formulary, to retain the decision-making authority for researching and developing a formulary for their patients. Flexibility should be built into this process to allow for individual physician and patient variation. The lead HMO regulatory agency should oversee the medical group's administrative capacity and ability to bear the financial risk for managing the pharmacy benefit.
b. Health plans that choose to retain the pharmacy benefit and develop a formulary for their members should include input from practicing plan physicians, specialty societies and other relevant data when composing the formulary.

C. Extend Accountability for Medical Decisions

Some feel that HMOs or other managed care organizations that participate directly in medical decisions that can be shown to negligently affect clinical outcomes, should be jointly responsible for liability only to the extent that each party's negligence contributes to an adverse outcome. To ensure limited impact on costs, award limits are necessary. Limits that apply to cases against an individual physician may not be appropriate to cases against an organization.

Shared responsibility for negligence contributing to an adverse outcome would be an extension of civil liability for the individual physician to civil liability for the HMO or managed care organization. This extension reflects the paradigm shift in the market whereby with the introduction of managed care, accountability for some medical decisions has shifted from the individual physician to the medical group in some cases and to the HMO in other cases. As risk is shifted, accountability for risk should be shifted correspondingly.

The regulatory oversight of medical groups, IPAs and other entities practicing medicine is discussed in the Task Force paper on Government Regulation and Oversight of Managed Health Care.

Recommendation 3:

The Task Force recommends to the Congress and the President that:
The ERISA statutes be revised to allow both the treating physician and the relevant health plan to be jointly responsible and liable for malpractice to the extent that each party's negligence contributes to an adverse outcome. This liability should be subject to appropriate (MICRA) limits to avoid creating incentives for costly lawsuits.

D. Clarify the Benefit Language in Health Insurance Contracts

Benefit language has traditionally relied on vague terms; health plans have covered most things thought to be "medically necessary" or "appropriate" by providers or that met a "community standard." Since no consensus exists as to whether making benefit language more precise will lead to improved quality, improved health outcomes, improved functional outcomes and better adherence to the scientific basis of treatment decisions, further study is needed.

A "blue ribbon" panel should study the issues inherent in changing benefit language from vague, imprecise terms to language intended to maximize quality outcomes, health outcomes, functional outcomes and the scientific underpinnings of treatment decisions while controlling costs. The work group should include a wide group of stakeholders in the health care industry including providers, patients and health plans, as well as experts in this complex area.

Debate about coverage and treatment decisions is not complete without more discussion about experimental treatments and therapies. The Friedman-Knowles bill makes provision for appeals after an experimental treatment decision is denied. However, the question of when a treatment crosses the line from experimental to accepted and non-experimental remains. It would be desirable for an independent, expert review panel of physicians and health plans to review the scientific findings to determine when there is sufficient evidence to reclassify therapies from experimental to accepted practice. Presently, a consistent, industry-wide process for this evaluation does not exist.

Recommendation 4:

a. Create a "blue ribbon" public/private work group of major stake-holders to study changing the benefit language in health plan contracts. The panel should have a state-wide strategy for implementing benefit language changes within two years. The State should require that implementation of these changes to be phased in within two subsequent years.

b. Encourage the California Medical Association (CMA), the California Association of Health Plans (CAHP), the American Medical Group Association (AMGA), the National IPA Coalition (NIPAC) and the California Healthcare Association (CHA) form an expert review panel of providers and health plans to review the scientific findings to determine when there is sufficient evidence to reclassify therapies from experimental to accepted practice. While there is also some logic to elevating this function to a national level, at this point, it makes sense to pilot the panel in California before giving the initiative broader exposure.

WHAT IS MEDICAL NECESSITY: WHO PRACTICES MEDICINE?

APPENDIX

I. INTRODUCTION

Providers and other appropriately credentialed health professionals operating within their scope of practice, in consultation with their patients about personal preferences are most qualified to make medical decisions. However, neither providers nor medical science are perfect. The quality of medical decisions can and should be improved by stimulating the research and application of scientifically based outcome studies that consider both clinical and cost effectiveness (See the New Quality Information Development paper). Encouraging valid and reliable, evidence-based medicine will reduce unwanted practice variation outcomes and cost. As practice variation declines, quality will increase, and patients, in aggregate, will receive better care.

Continuously improving the quality of medical decision making should drive the process of care. The clinical process of care includes diagnostic evaluations, clinical judgments, surgery, therapies and drugs. Unqualified individuals and organizations, whether they be HMO employees or legislative bodies, regardless of how well-meaning, should not be practicing medicine. Politics should not determine medical practice. Appropriately credentialed professionals practicing scientific, evidence-based medicine should be the arbiters of cost-effective medical care. They should also be responsible for continuously improving the quality of medical care.

To improve health and medicine, small, incremental process adjustments as well as major innovations are needed. The practice of medicine in general and within managed care in particular, needs the flexibility that the private sector can provide to make improvements. However, if the private sector fails to make changes in an equitable and responsible way, regulation may be necessary.

Sometimes, despite everyone's best effort, the practice of medicine produces an adverse outcome. When all reasonable dispute resolution techniques have been applied and failed, patients and consumers need statutory protection. The current ERISA laws do not afford sufficient or equal consumer protection for all privately insured patients and consumers. Those individuals covered by private sector, employer plans are less well protected than individuals covered by federal, state or municipal governments or through individual coverage. To correct this imbalance would require changes in the ERISA laws.

We have underway in this country a large natural experiment: some employers are covered under ERISA, some are not. This experience should be carefully studied to find out how the lack of ERISA preemption affects costs and frequency of litigation. This analysis would strengthen the debate about appropriate limits in damage awards.

A. Prior Authorization /Concurrent Review Process as a Management Tool

There are pros and cons to prior authorization/concurrent review. These techniques were first created by the managed care industry as a tool to curb the "cost-unconscious" practice of medicine. They were necessary when first created to raise providers' awareness that the cost of care needed to be considered in the practice of medicine. They were also a useful tool for HMOs and other managed care organizations to use to better understand, inform and control a rapidly growing and changing industry. Prior authorization/concurrent review was one of many tools for managing consumer expectations. Consumers with unlimited, low cost indemnity insurance (low cost to them) had been accustomed to receiving unlimited services at little or no financial or inconvenience cost to themselves. Prior authorization/concurrent review was used to sensitize patients and consumers that health care had limits. Services being prescribed by clinicians and requested by patients carried a cost and costs were spiraling out of control.

Some have argued that prior authorization/concurrent review is a key element separating managed care from traditional indemnity insurance. In addition to controlling costs, prior authorization/concurrent review can, in some cases, strengthen the quality of care by identifying procedures, tests or other treatments that may be unnecessary or contribute to errors. One HMO medical director testified to the Task Force that prior authorization procedures prevented unnecessary hysterectomies for women who may have wanted to have children. Prior to doing a test or a procedure, the reviewer, who may be an HMO medical director, or more likely in California a medical group or IPA medical director, is, in theory, given the opportunity to measure an impending medical decision against outcomes research, practice guidelines and relevant clinical algorithms. This should ultimately work to patients' benefit. The evidence of effectiveness is mixed. The perception that treatment decisions are being reviewed by an appropriately credentialed physician, with adequate knowledge of the case at hand, is also mixed. The public perception is that the health plan reviewers are a heterogeneous group with mixed qualifications and prior authorization/concurrent review sometimes focuses too heavily on cost and causes inappropriate delays or denials in care without due medical cause

B. Variation in Medical Practice Patterns Suggests Some Review is Appropriate

There is significant variation in medical practice. The Dartmouth Atlas of Health Care charts wide variation in both the uses of diagnostic and surgical procedures for individuals with coronary artery disease, prostate and breast cancer and back pain. The Atlas reports a fourfold variation in per capita rates of coronary artery bypass graft (CABG) surgery in 1992-93 for Medicare patients from one area to another. Researchers also found an eightfold discrepancy in rates of radical prostatectomy, a surgical treatment for early stage prostate cancer. Breast sparing surgery for breast cancer varied more than 33-fold. This degree of practice pattern variation raises important and complex questions. "Which rate of surgery or therapy is right?" "Are some patients being treated more conservatively with the same or better outcomes?" "Do certain rates of surgery

or therapy reflect patient preferences and values more than others?" "What is the effect on a population's health?" Variation also suggests that sometimes providers differ on what is medically necessary. In addition, some patients want unnecessary services. One doctor complained to the Task Force that some patients demand diagnostic tests or drugs for which no medical indication exists. The behavior of both physicians and patients is frequently drivey by the inherent uncertainty in medical care. The need to reduce this uncertainty and consequent vriation is compelling and very challenging.

Variation in medical practice has also been accompanied by variation in the payment for certain surgeries and treatments. For example, Medicare paid $5966 per enrollee in Miami in 1993, nearly twice the rate paid per enrollee in San Jose, adjusted for age and utilization factors. From a population perspective, this represents a problematic allocation of national resources.

Given the wide variation that exists, there is legitimacy in HMOs seeking to influence medical practice in the direction of what more conservative providers do to produce equivalent or better outcomes. As a tool, prior authorization/concurrent review retains serious merit. However, its application has been problematic. In some cases prior authorization/concurrent review has diminished quality by distancing the medical decision maker from the patient, introduced untimely delays in the process of care, and created an additional layer of bureaucracy with which treating providers must contend. In general, patients and providers consider the additional step of obtaining prior authorization/concurrent review to be onerous, inconvenient and detrimental to the quality of care. This has particularly been the case for adults and children with chronic disease who may be required to obtain approvals regularly. Some HMOs and other managed care plans have delegated prior authorization/concurrent review to their contracting medical groups, IPAs or other utilization management designees. It seems reasonable to suppose that prior authorization/concurrent review by medical groups and IPAs has generally worked better than health plan review.

When there is no medical group or IPA to whom to delegate, other modification may be needed. One HMO has adopted a "gold standard" approach whereby a physician's medical decisions are reviewed retrospectively over a period of time to ascertain patterns of care and consequent outcomes. If the physician's range of referral patterns are appropriate and outcomes are good, the physician is considered to have met the "gold standard" and the HMO ceases to require prior authorization/concurrent review. This approach seems makes sense when the HMO contracts with providers on a fee-for-service basis and the HMO has practice pattern data. It might also be applicable in the case of review within a medical group.

Large HMOs have argued that the "gold standard" approach is not a feasible solution for them because they pay their medical groups on a capitated basis and do not receive information about patterns of care from the groups. Some medical groups and IPAs have argued that if decision authority has been delegated, the plans shouldn't need this information. This particular problem could be solved if medical groups and plans were willing to share this information. (See New Quality Information Development paper.) Large plans would then have the opportunity to review physician practice patterns against a very large data set and be able to discern more statistically relevant patterns and ranges of variation in treatments and outcomes, increasing opportunities to improve the quality of care. Medical groups would also have the opportunity to better understand large-scale variations in practice patterns and identify areas to improve the quality of patient care.

Other alternatives to prior authorization/concurrent review are possible. There is room in the marketplace for a variety of innovative responses and expedited referral programs. ,

Assuming the current prior authorization process/concurrent review process may be contributing to doctor and patient dissatisfaction, in some respects, it would be desirable to modify it. For example, it would be desirable for some patients with chronic illness to receive their primary care from a specialist with the appropriate specialty credentials. In addition, some children with chronic disease would benefit from receiving their primary care from pediatric specialists in the chronic disease.. For both adults and children it would be in their best interest for the specialist to have experience and training in primary care and to regularly provide primary care to patients with chronic disease.

Who should determine which chronic diseases should have prior authorization/concurrent review replaced by retrospective review of outcomes and patterns of care? What should be the standard of care against which providers' patterns are measured? There is not one answer to these questions. Health plans would need to craft solutions and policies that fit their culture and the culture of their contracted medical groups. Practice guidelines, clinical pathways, pre-credentialing of providers, retrospective utilization review and outcome studies are potentially efficient substitutes for prior authorization/concurrent review. Exactly how they are applied would better be left to the health plans to determine in cooperation with those purchasing their services. This type of change could have a cost impact on the plan, medical group and premium. It would be wise to implement modifications incrementally so that changes can be evaluated for both clinical and cost effectiveness.

Patients with catastrophic diseases deserve special consideration. For example, in certain cancer cases treatment and therapy is time sensitive and delays or denials of care can have severe and unintended consequences. In many of these cases there are existing, accepted and respected clinical guidelines. (needs FN) Prior authorization/concurrent review should not be a barrier to care in these cases.

In all situations, it is important to recognize that medical science and practice are constantly changing and a rigid codification of medical practice should be avoided. Implementing these changes by enacting a law would stifle the creation of innovative processes. To encourage innovation, avoid rigidity, yet monitor compliance is not easy.

Recommendation 1:

a. The Task Force recommends to the major public and private purchasers that they incorporate provider pre-credentialing and the use of practice guidelines, clinical pathways, retrospective review (as opposed to prior authorization/concurrent review) and outcomes based data into their contracts with health plans.
b. The Task Force recommends to the health plans and the medical groups, IPAs and their designees that they develop statistically valid data on patterns of care and patient outcomes. These data sets should then form the basis on which alternatives to prior authorization can be based.
c. The Task Force recommends to the health plans, medical groups, IPAs and their designees, that they develop and implement strategies that allow providers, demonstrating a "gold standard" range of practice, to practice medicine with automatic approval. Health plans should develop appropriate and periodic review mechanisms to ensure that providers continue to demonstrate a "gold standard" range of practice.
d. The Task Force recommends to the health plans that they eliminate prior authorization/concurrent review for patients with catastrophic conditions (for example pediatric oncology patients) being treated by pre-credentialedproviders.
e. The Task Force recommends to the legislature that: if by 2002 the private sector has not sufficiently modified the prior authorization/concurrent review process to recognize "gold standard" ranges of care or an equivalent modification , the lead HMO regulatory agency should make the necessary changes a requirement of health plan licensure.

C. Pharmaceuticals are a Necessary Part of Medical Practice

The appropriate practice of medicine integrates clinical judgment, diagnostic evaluations, surgery, therapies and drugs. Often the use of pharmaceuticals can improve quality and reduce costs by avoiding unnecessary procedures or hospitalizations. Victor Fuchs, a health economist, wrote, "Drugs are the key to modern medicine. Surgery, radiotherapy, and diagnostic tests are all important, but the ability of health care providers to alter health outcomes ... depends primarily on drugs."

The treating provider should know the most about a patient's medical history, including which drugs have or have not been successful. Therefore, a strong case could be made that the choice of drugs should be under the control of the treating physician. However, pharmaceutical costs are rising rapidly; formularies are a necessary tool to manage them. To lower pharmaceutical costs and maintain affordable drug coverage, a strong case could also be made that the individual physician's choice of drugs should be informed, guided

and perhaps constrained by a committee of his or her peers. The committee could study the research pharmacology literature, analyze the group's own data, if any, consult with pharmacists and other experts, and create a formulary, or list of drugs based on scientific evidence that identifies "best practices" or guidelines for prescribing certain medications for specific conditions. Hospitals, medical groups, HMOs and Pharmacy Benefit Management (PBM) companies have such Pharmacy and Therapeutics (P & T) Committees and many have formularies.

In one model, a large, integrated multi-specialty medical group (or a group of groups) has a P&T committee that can be supported by medical and surgical specialists, pharmacists and statisticians, and evaluate drugs and their relevant applications. This P & T committee would have the resources and expertise to make selections and then meet with doctors in their specialty to educate them on the reasons for the committee's choices. If this medical group accepts financial risk for the cost of drugs, one could say that incentives are properly aligned because the group has a strong incentive to choose effective drugs. This integrated, medical group model would likely have the advantage that the doctors would comply because they or their partners made the choices. The involvement of practicing physicians in formulary development is key.

Some, typically smaller medical groups contract with a (PBM) to create and refine the group's formulary. While this would provide a single formulary for the group, it may not enjoy the same level of acceptance among the group's providers. In addition, since some PBMs are owned by pharmaceutical manufacturers, these PBMs may have a conflict of interest in selecting drugs for the medical group's formulary.

In an alternative HMO model, an HMO contracts with several medical groups and IPAs, forms a P&T committee and creates its own formulary. The HMO assumes the financial risk for the cost of drugs, and negotiates discounts with the manufacturers. A key difference in the HMO model and the small medical group/PBM model is the P & T committee is at a distance from the treating providers. P & T members do not have to face disappointed patients when drugs do not have the intended effect. The HMO's incentive may be to minimize pharmacy costs rather than to choose more effective drugs and minimize the total cost of care.

In an HMO based formulary, where the treating providers have not been involved in the decisions and the HMO is at financial risk for the costs, and not the providers, economic theory would predict that the doctors have less reason to comply with the formulary. This would weaken the bargaining power of the HMOs. If the drugs selected for the formulary are not effective, the medical group would bear the cost of drugs outside the formulary as well as the increased cost of medical care for patients who require more steps in their treatment because of ineffective drugs, at least in the short run. In this case the HMOs would be rewarded financially while patient care and the medical groups would be compromised.

Another problem of the HMO-based formulary is a consequence of the fact that the average medical group in California has contracts with 15 managed care plans . Providers have to figure out which health plan covers their patient, then which drugs are on its formulary, and then spend time on the phone requesting exceptions. This is bound to raise administrative costs and complexity. The situation can be worse--indeed bordering on the impossible--for the doctor in individual practice who belongs to several IPAs, each of which contracts with 15 different managed care plans.

Some favor abolishing formularies, others locate the decision making power and financial risk with the participating medical groups and IPAs, or the PBMs with which they contract. It seems reasonable to delegate to them the decision making power and financial risk for pharmaceuticals where medical groups can demonstrate to the lead HMO regulatory authority (now DOC) both financial capacity to bear the risk and administrative capacity to manage the drug benefit program. Because of the large costs involved, it is likely that only fairly large groups would be able to undertake this. More likely, groups of medical groups or IPAs would form for this purpose.

Recommendation 2:

Therefore, the Task Force proposes the following recommendation:

a. Health plans should permit medical groups, or groups of groups, capable of assuming the management and financial risk for a drug formulary, to retain the decision-making authority for researching and developing the formulary for their patients. The lead HMO regulatory authority should oversee the medical group's administrative capacity and ability to bear the financial risk for managing the pharmacy benefit.
b. Health plans that choose to retain the pharmacy benefit and develop a formulary for their members should include input from practicing plan physicians, specialty societies and other relevant data when composing the formulary.

D. Medical Decision Making and Accountability

The Medical Practice Act, a state law, assures that only qualified professionals make medical decisions. The Act defines the regulatory structure for licensure and allows for the Medical Board to discipline individuals if their practice endangers patients. Patients have redress for negligent actions by providers through the tort system. Current law states that parties that participate directly in medical decisions that negligently affect clinical outcomes are responsible for liability. (footnote) However, the Employee Retirement Income Security Act of 1974(ERISA), a federal law, protects most health plans from this responsibility in the case of private sector employees and their families by allowing the plans to claim that utilization decisions are not medical decisions, rather, administration of an employee benefit. The courts have upheld this defense in general. In California, if courts have held otherwise, plaintiff awards have been subject to the Medical Injury Compensation Reform Act (MICRA), a state law, which imposes a $250,000 limit on the pain and suffering component of the damage award. There is no limit on economic damages. Currently, ERISA plaintiffs are only eligible to recover money for the covered benefit and are not able to collect compensatory or punitive damages. ERISA limitations only permit plaintiffs to collect damages from an individual provider, and not from a medical group, IPA or health plan.

Some courts in other states have held that a health plan and its medical director can be liable for denying coverage for certain procedures and can be disciplined by the state Board of Medical Examiners. Some people in California would like to impose the same standard.

Historically, the practice of medicine has relied upon regulation and civil liability controls to ensure the quality of care. Currently, HMOs are held accountable for their medical decision-making by the DOC for the approximately 40-50% of the market that is not covered under ERISA. While some HMOs delegate treatment and decision-making responsibilities to the medical groups, IPAs and other utilization management designees with whom they contract, the HMOs retain the responsibility for ensuring that their contractors comply with all of the provisions of the Knox-Keene Act. Currently there is no designated state regulatory authority that directly oversees the practice of medicine by medical groups/IPAs, as organizations. For more discussion of the regulatory oversight of medical groups, IPAs and other entities practicing medicine, please see the Task Force paper on Government Regulation and Oversight of Managed Care.

ERISA laws do not apply to insured federal, state, municipal and self-employed individuals. As noted above, the preemption applies to the approximately 50-60% of the market, or those insured by the private sector in self-funded plans, that are covered under ERISA. It is this latter group that does not enjoy the same level of civil liability protection under the ERISA laws. More importantly, before any tort controls come into play, a patient must suffer an egregious and negligent event. All parties would benefit if the egregious and negligent event never happened in the first place.

Some feel that HMOs or other managed care organizations that participate directly in medical decisions that can be shown to negligently affect clinical outcomes, should be jointly responsible for liability only to the extent that each party's negligence contributes to an adverse outcome. To ensure limited impact on costs,

award limits are necessary. Limits that apply to cases against an individual physician may not be appropriate to cases against an organization.

We have underway in this country a large natural experiment: some employers are covered under ERISA, some are not. This experience should be carefully studied to find out how the lack of ERISA preemption affects costs and frequency of litigation. This analysis would strengthen the debate about appropriate limits in damage awards.

Shared responsibility for negligence contributing to an adverse outcome would be an extension of civil liability for the individual physician to civil liability for the HMO, medical group, IPA or other utilization management designee. This extension reflects the paradigm shift in the market whereby with the introduction of managed care, accountability for some medical decisions has shifted from the individual physician to the medical group in some cases and to the HMO in other cases. As risk is shifted, accountability for risk should be shifted correspondingly.

Recommendation 3:

Therefore, the Task Force recommends to the Congress and the President that:

a. The ERISA statutes should be revised to allow both the treating physician and the relevant health plan to be jointly responsible and liable for malpractice to the extent that each party's negligence contributes to an adverse outcome. This liability should be subject to appropriate (MICRA) limits to avoid creating incentives for costly lawsuits.

E. Clarify the Benefit Language in Health Insurance Contracts

In discussions of health insurance, contract language, and managed care, there has been extensive debate about the pros and cons of medical necessity decisions, coverage decisions, experimental treatments and the existing language of most benefit contracts. , Benefit language has traditionally relied on vague terms. Health plans have covered most things thought to be "medically necessary" or "appropriate" by providers, or that met a "community standard." Vague contract language, open to multiple interpretations has received added attention with the growth of managed care and the introduction of new, expensive and experimental medical treatments such as autologous bone marrow transplants (ABMT) for breast cancer. There has been a great deal of disagreement about what these terms mean. In cases where payers have not paid for something, expensive litigation has often ensued.

In 1996 the California debate over "medically necessary" experimental treatments and procedures, and the appropriateness of subsequent litigation with very large damage awards led to the passage of AB 1663. Known as the Friedman-Knowles bill for Experimental Treatment Coverage: Independent Review, this law establishes a process for the review of coverage denials for experimental treatment procedures by independent medical experts, commonly known as independent third party reviewers. Reviewed decisions are then binding on the health care service plan or insurer. Although enacted in 1996, the Friedman-Knowles bill will not become effective until July 1, 1998 in order for the DOC to accredit independent third party reviewers before they are asked to examine specific cases. This new law creates another vehicle for dispute resolution that is reactive rather than pro-active. Philosophically it would be better to prevent disputes from happening in the first place. Changing benefit language and the criteria for benefit decisions to improve quality while reducing costs would be a step in this direction.

Further study is needed to determine whether changing the benefit language from vague, imprecise terms to language intended to maximize quality, improve health outcomes, improve functional outcomes and strengthen the scientific underpinnings of treatment decisions while controlling costs will work. All stakeholders in the health care industry including providers, patients and health plans, as well as experts in this complex area should be involved in order to reach a broadly based consensus on defining a new benefit language and the criteria to use for coverage decisions. Further study and consensus is also needed on how

to isolate coverage decisions from treatment decisions. More science is needed to guide the creation of the database that should be used to determine the appropriateness and effectiveness of one treatment in deference to another. Consensus is needed before regulatory or statutory changes to current contract language can be recommended. .

Debate about coverage and treatment decisions is not complete without more discussion about experimental treatments and therapies. The Friedman-Knowles bill makes provision for appeals after a treatment decision is denied. However, the question of when a treatment crosses the line from experimental to accepted and non-experimental remains. It is an issue that affects potentially everyone, not just managed care participants. From a managed care perspective though, it would be desirable for an independent, expert review panel of physicians and health plans to review the scientific findings to determine when there is sufficient evidence to reclassify therapies from experimental to accepted practice.

Recommendation 4:

Therefore, the Task Force proposes the following recommendation:

a. Create a "blue ribbon" public/private work group of major stake-holders to study changing the benefit language in health plan contracts. The panel should have a state-wide strategy for implementing benefit language changes within two years. The State should require that implementation of these changes be phased in within the subsequent two years..

b. Encourage the California Medical Association (CMA) and the California Association of Health Plans (CAHP), the American Medical Group Association (AMGA), the National IPA Coalition (NIPAC), and the California Healthcare Association (CHA) to form an expert review panel of providers and health plans to review the scientific findings to determine when there is sufficient evidence to reclassify therapies from experimental to accepted practice. While there is also some logic to elevating this function to a national level, at this point, it makes sense to pilot the panel in California before giving the initiative broader exposure.